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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,171	PATI ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-15, 17-20* is/are rejected.

7)☒ Claim(s) *14,16 and 19* is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 12/23/03, are acknowledged. Amended claims 1-4 and 7-12 as well as new claims 13-20 are acknowledged.

Applicant's arguments, filed 12/23/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4 and 6-20 are herein under examination.

Claim Objection

Claims 14 and 19 are objected to because of the following minor informalities: Claim 14 recites the phrase "wherein said website customer interface wherein said request" which is awkward wording of two wherein statements that fails to establish their relationship to each other. Claim 19 contains two steps (a) and (b) wherein the independent claim 1 already contains steps denoted with letters (a) and (b). Correction is suggested by amending the two steps of claim 19 to steps (c) and (d). Appropriate correction is requested. These objections are necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended claim 11 to recite "or agent" which does not appear to have adequate support in the specification on pages pointed out by Applicants (page 5, lines 6-8; page 6 lines 8-10 and 16-26). The specification states on page 6, lines 8-10, "If DirectGenomics does not provide one or more of the services or products, the company rankings are used to select a provider." This suggests that DirectGenomics may be used as an "agent" of sorts, but this scope of the claim does not equate to "agent" which can be broadly interpreted to encompass other agents besides DirectGenomics. Due to the introduction of the phrase "or agent" in instant claim 11 which appears to lack written support, as filed 11/23/03, this phrase is considered NEW MATTER. Claim 12 is also rejected due to its dependency from claim 11. This rejection is necessitated by amendment.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 8 is maintained and newly applied to claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 8 recites the phrases "substantially complementary" and "is complementary to a sequence that has at least about 70% sequence identity" which are vague and indefinite. The claim still does not adequately define the phrase which could mean the complementarity is at least 70% similarity and of the same length of the claimed sequence, or at least 70% similarity and only a fragment of the claimed sequence, or any other scenario. Further definition of the degree of complementarity to the sequence is required. Applicants submit that the claim has been amended so that the complementarity includes is at least 70% sequence identity compared to the second single-stranded target polynucleotide; however, the broad and reasonable interpretation of the claim appears to encompass more than Applicants submission which still poses the vague and indefinite issue. This rejection is maintained and necessitated by amendment.

Claim 8 recites the phrases "or a homologue thereof" and "wherein said homologue has at least about 70% sequence identity" which are vague and indefinite. The claim still does not adequately define the phrase which could mean at least about 70% similarity and of the same length of the claimed sequence, or at least about 70% similarity and only a fragment of the claimed sequence, or any other scenario. Further definition of the degree of homology to the

sequence is required. Applicants submit that the claim has been amended so that the homologue is at least 70% homologous to first single-stranded target polynucleotide; however, the broad and reasonable interpretation of the claim appears to encompass more than Applicants' submission which still poses the vague and indefinite issue. This rejection is maintained and necessitated by amendment.

Claim 13 recites the phrase "comprises at least one of a nucleic acid sequence field and a pointer to a nucleic acid sequence" which is vague and indefinite. One interpretation is that the input comprises at least one of either a nucleic acid sequence field or a pointer. Another interpretation is that the input comprises at least nucleic acid sequence field and at least one pointer. A third interpretation is that the input comprises at least one nucleic acid sequence field as well as only one pointer. Clarification of this issue, via clearer claim wording, is requested. This rejection is necessitated by amendment.

Claim 13 recites the phrase "said input" which is rejected due to a lack of antecedent basis for this phrase. Correction of this lack of antecedent basis issue is requested. This rejection is necessitated by amendment.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-4, 6, 9, 11, and 12 is maintained and newly applied to new claims 13-15 and 17-19 under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (P/N 5,841,975) in view of Seilhamer et al. (WO 96/23078).

Layne et al. describe a method and apparatus for sharing integrated services with remote clients involving biological material (abstract, item 200 in Figure 7, and col. 11, lines 55-57). Layne et al. describe a customer generating commands (request) via a computer communication program link and the internet (websites) and sending specimens to an automated lab (abstract; Figure 4; col. 8, lines 30-35; and col. 15, lines 22-25). Layne et al. describe the customer is enabled to define the processes to be performed by entering information into the program via control tools (col. 8, lines 30-32). Layne et al. describe obtaining and transmitting results, which is reasonably interpreted as more than one product or service, to the remote client (abstract). Layne et al. also describe creating and entering output and analyses for the results (report) into a database as seen in Figure 4. Layne et al. depict this process as circular and continuous (Figure 4) which suggests that multiple, including second requests (note the claims do not require the first and second nucleic acid sequences to necessarily be different), can be made by the customer

as stated in claim 3. Layne et al. describe how the remote customer can have the data stored into a database and request analyses to be performed on data generated by their and other users' data on the database (col. 8, lines 45-51 and col. 11, lines 5-9). Layne et al. describe using instruments in an automated test instrument suite which offers selections of standardized tests, so if assays of biological specimens are desired, then selections of standardized assays are offered within process control tools including a database (Figure 6 and col. 10, lines 41-46) which represents a pull-down menu as stated in new instant claim 13. Layne et al. describe researchers entering information about specimens, treating agents (drugs), cell cultures, data (results), and other items (col. 10, lines 52-63) which represents a report as stated in new instant claim 15. Layne et al. describe ascertaining amount of materials for a test and checking either that it can proceed or report that it cannot do so and state a cause (col. 9, lines 21-26). Layne et al. describe evaluating whether specimens and assays meet quality control standards (col. 11, lines 9-12) which represents a verification that the customer is in good standing, as stated in new instant claim 17. Layne et al. describe privileges designating who has permission to view or use the data which may include the researcher only, certain collaborators, or unrestricted access by all (col. 11, lines 23-29) which represents a private or semi-private secured transmission line, as stated in new instant claim 18. Layne et al. do not describe the nucleic acid clone product ordered from the customer that is the noted specie election in the instant application.

Seilhamer et al. describe obtaining cDNA from a customer as well as storing relevant supplier information in a table which is stored in a database (page 9, lines 25-30). Seilhamer et al. describe performing a cloning process on the cDNA (Figure 2 and page 9, lines 31-32). As the claims do not mention that the "at least two genomics products" must be different from each

other, Seilhamer et al. describe multiple clones which may or may not be different (page 15, lines 6-10). In Figure 2, Seilhamer et al. depict the cloning process followed by sequencing which is stored in a database (page 14, third paragraph) and sequence comparison (page 15, first paragraph) which is reasonably interpreted to mean that searchable genomic data were created as stated in claim 2. Seilhamer et al. describe the sequences may be compared to known sequences in genetic databases (page 15, first paragraph to page 17, first paragraph). Seilhamer et al. describe during the sequence comparison process, the multiple clones may contain all or parts of the same gene/allele (page 15, first paragraph) which is reasonably interpreted as checking for wholly or partially redundant information within the databases as stated in claim 12. This also suggests the clones may represent a subset of a gene family as stated in claim 6. Seihamer et al. describe that information associated with the steps in Figure 2 (including sequence comparison) is stored in a database (page 6, lines 6-9) which is reasonably interpreted to include the updating step in claim 12. Seilhamer et al. describe using an interface with an integrated ethernet network (Figure 1). Seilhamer et al. describe various fields, such as COLLABORATOR_ID (110) (customer identification number), BIO_SOURCE_ID (130) (field for nucleic acid sequence), and CULTURE_ID (140) (field for genomic product), cDNA CONSTRUCTION_ID (170) (field for another genomic product) (Figure 3A and B) and CLONE_ID (Figure 4) as now stated in instant claims 1, 9, and 11. Seilhamer et al. describe suppliers and vendors (Figures 3A and 6). Seilhamer et al. describe databases that include nucleic acids, proteins, and motifs (page 3, lines 36-37).

Layne et al. state their apparatus and method satisfies a need to provide a wide variety of adaptable services to globally-distributed remote clients (col. 15, line 66 to col. 16, line 10).

Layne et al. state there is a need to integrate capabilities of available automated equipment to permit processes to be performed instead of solely relying on special-purposes devices (col. 16, lines 1-4). Seilhamer et al. state that most analysis on genetic information was performed using chemical methods in a laboratory (page 1, lines 27-28). Seilhamer et al. state computerized research tools at the time only performed limited comparisons to sequence information and state a need to store and manipulate diverse information involving cDNA sequences and the cells from which they were derived in order for scientists to analyze data efficiently in diagnostic and drug development research (page 1, line 33 to page 2, line 5). A person of ordinary skill in the art would have been motivated to enhance the integrated internet (website) services stated by Layne et al. by including additional features in the method to further increase the efficiency and availability of research materials, as stated by Seilhamer et al., to globally-distributed remote clients. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the nucleic acid clone supplies and associated sequence comparison information and field identifiers (as stated by Seilhamer et al.) in a manner to be available to remote clients (as stated by Layne et al.) as this would provide a more efficient and global use of tools for diagnostic and drug development research as stated by Seilhamer et al. and Layne et al.

Thus, Layne et al., in view of Seilhamer et al., motivate claims 1-4, 6, 9, 11, 12-15, and 17-19.

Applicants summarize the limitations of instant claims 1, 9, 10, and 11. Applicants submit that neither Layne et al. nor Seilhamer et al. describe a request that comprises a website

customer interface. This is found unpersuasive as it is pointed out above where the new limitations can be found in the prior art references, so that the 35 U.S.C. § 103(a) prior art rejection is maintained using references Layne et al. in view of Seilhamer et al. This rejection is necessitated by amendment.

The rejection of claims 1-4 and 6-12 is maintained under 35 U.S.C. 103(a) and newly applied to new claims 13-15 and 17-20 as being unpatentable over Layne et al. (P/N 5,841,975) in view of Seilhamer et al. (WO 96/23078) and Pati et al. (WO 99/37755).

Layne et al. describe a method and apparatus for sharing integrated services with remote clients involving biological material (abstract, item 200 in Figure 7, and col. 11, lines 55-57). Layne et al. describe a customer generating commands (request) via a computer communication program link and sending specimens to an automated lab (abstract; Figure 4; col. 8, lines 30-35; and col. 15, lines 22-25). Layne et al. describe the customer is enabled to define the processes to be performed by entering information into the program via control tools (col. 8, lines 30-32). Layne et al. describe obtaining and transmitting results, which is reasonably interpreted as more than one product or service, to the remote client (abstract). Layne et al. also describe creating and entering output and analyses for the results (report) into a database in Figure 4. Layne et al. depict this process as circular and continuous (Figure 4) which suggests that multiple, including second requests (note the claims do not require the first and second nucleic acid sequences to necessarily be different), can be made by the customer as stated in claim 3. Layne et al. describe how the remote customer can have the data stored into a database and request analyses to be performed on data generated by their and other users' data on the database (col. 8, lines 45-51

and col. 11, lines 5-9). Layne et al. describe using instruments in an automated test instrument suite which offers selections of standardized tests, so if assays of biological specimens are desired, then selections of standardized assays are offered within process control tools including a database (Figure 6 and col. 10, lines 41-46) which represents a pull-down menu, as stated in new instant claim 13. Layne et al. describe researchers entering information about specimens, treating agents (drugs), cell cultures, data (results), and other items (col. 10, lines 52-63) which represents a report as stated in new instant claim 15. Layne et al. describe ascertaining amount of materials for a test and checking either that it can proceed or report that it cannot do so and state a cause (col. 9, lines 21-26). Layne et al. describe evaluating whether specimens and assays meet quality control standards (col. 11, lines 9-12) which represents a verification that the customer is in good standing, as stated in new instant claims 17 and 20. Layne et al. describe privileges designating who has permission to view or use the data which may include the researcher only, certain collaborators, or unrestricted access by all (col. 11, lines 23-29) which represents a private or semi-private secured transmission line, as stated in new instant claims 18 and 20. Layne et al. do not describe the order from the customer which is a nucleic acid clone (the noted specie election in this application) or the use of a recombinase mediated process.

Seilhamer et al. describe obtaining cDNA from a customer as well as storing relevant supplier information in a table which is stored in a database (page 9, lines 25-30). Seilhamer et al. describe a cloning process is performed on the cDNA (Figure 2 and page 9, lines 31-32). As the claims do not mention that the "at least two genomics products" must be different from each other, Seilhamer et al. describes multiple clones which may or may not be different (page 15, lines 6-10). In Figure 2, Seilhamer et al. depict the cloning process followed by sequencing

which is stored in a database (page 14, third paragraph) and sequence comparison (page 15, first paragraph) which is reasonably interpreted to mean that searchable genomic data was created as stated in claim 2. Seilhamer et al. describe the sequences may be compared to known sequences in genetic databases (page 15, first paragraph to page 17, first paragraph). Seilhamer et al. describe the multiple clones may contain all or parts of the same gene/allele (page 15, first paragraph) which is reasonably interpreted as checking for wholly or partially redundant information within the databases as stated in claim 12. This also suggests the clones may represent a subset of a gene family as stated in claim 6. Seihamer et al. describe that information associated with the steps in Figure 2 (including sequence comparison) is stored in a database (page 6, lines 6-9) which is reasonably interpreted to include the updating step in claim 12. Seilhamer et al. describe various fields, such as COLLABORATOR_ID (110) (customer identification number), BIO_SOURCE_ID (130) (field for nucleic acid sequence), and CULTURE_ID (140) (field for genomic product), cDNA CONSTRUCTION_ID (170) (field for another genomic product) (Figure 3A and B), as now stated in instant claims 1, 9, and 11.

Pati et al. describe a method for targeting sequence modifications in one or more genes of a related family of genes using enhanced homologous recombination techniques (page 1, lines 6-7). Pati et al. describe a method of isolating and identifying members of homologous sequence families (page 1, lines 7-9). Pati et al. describe the provision of a composition comprising a recombinase and a plurality of pairs of substantially complementary single-stranded targeting polynucleotides and isolating the nucleic acid (page 4, fourth paragraph to page 5, third paragraph).

Layne et al. state their apparatus and method satisfies a need to provide a wide variety of adaptable services to globally-distributed remote clients (col. 15, line 66 to col. 16, line 10). Layne et al. state there is a need to integrate capabilities of available automated equipment to permit processes to be performed instead of relying solely on special-purposes devices (col. 16, lines 1-4). Seilhamer et al. state that most analysis on genetic information was performed using chemical methods in a laboratory (page 1, lines 27-28). Seilhamer et al. state computerized research tools at the time only performed limited comparisons to sequence information and there was a need to store and manipulate diverse information involving cDNA sequences and the cells from which they were derived in order for scientists to analyze data efficiently in diagnostic and drug development research (page 1, line 33 to page 2, line 5). Pati et al. state techniques using enhanced homologous recombination were recently discovered which allow sequence modifications to be specifically targeted to virtually any genomic position (page 3, paragraph three). A person of ordinary skill in the art would have been motivated to enhance the integrated services stated by Layne et al. by including additional features in the method to further increase the efficiency and availability of research materials as stated by Seilhamer et al. to globally-distributed remote clients. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the nucleic acid clone supplies and associated sequence comparison information (as stated by Seilhamer et al.) using a specific cloning process involving recombinase in order to target specific genes in diseased organisms (as stated by Pati et al., page 6, last paragraph) in a manner that is available to remote clients (as stated by Layne et al.) as this would provide a more efficient and global use of tools for diagnostic and drug development research as stated by Seilhamer et al. and Layne et al.

Thus, Layne et al., in view of Seilhamer et al. and Pati et al., motivate claims 1-4 and 6-15 and 17-20. This rejection is necessitated by amendment.

Applicants traverse this 35 USC 103(a) rejection for the same reasons as the previously discussed 35 USC 103(a) rejection, including amended limitations of instant claims 1, 9, 10, and 11. Applicants submit that neither Layne et al., Seilhamer et al., nor Pati et al. describe a request that comprises a website customer interface. This is found unpersuasive as it is pointed out above where the new limitations can be found in the prior art references, so that the 35 U.S.C. § 103(a) prior art rejection is maintained using references Layne et al. in view of Seilhamer et al. and Pati et al. This rejection is necessitated by amendment.

Conclusion

No claim is allowed.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This objection is necessitated by amendement.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

March 30, 2004

Ardin H. Marschel 4/6/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER